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Issued August 4, 1915.

U. S. DEPARTMENT OF AGRICULTURE.

BUREAU OF ANIMAL INDUSTRY.

NOTICE OF HEARINGS ON PROPOSED REGULATIONS OF THE SECRETARY OF AGRICULTURE UNDER THE VIRUS-SERUM-TOXIN ACT OF 1913 (37 Stat., 832).

Commencing at 10 o'clock in the forenoon of August 23, 1915, hearings will be held in the board room of the Bureau of Animal Industry, fourth floor, No. 1358 B Street SW., in the city of Washington, upon proposed rules and regulations to be issued by the Secretary of Agriculture under the virus-serum-toxin act of 1913. A draft of the proposed regulations has been prepared and copies will be furnished those who are interested and who wish to take part in the discussion.

Commercial producers of viruses, serums, toxins, and analogous products intended for use in the treatment of domestic animals, State officials, stock raisers, veterinarians, and all other persons interested are invited to be present at the hearings. Opportunity for oral discussion will be afforded to as many as practicable. Written communications from those not attending will be considered; these should be addressed to the Chief of the Bureau of Animal Industry, Department of Agriculture, Washington, D. C. It is requested that arguments, suggestions, and criticisms be brief and definite, and refer specifically to particular sections of these regulations.

D. F. HOUSTON, *Secretary.*

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REGULATION 1.—DEFINITIONS.

SECTION 1. Paragraph 1. For the purpose of these regulations the following words, phrases, names, and terms shall be construed respectively to mean:

Paragraph 2. *The virus-serum-toxin act of 1913.*—"An act making appropriations for the Department of Agriculture for the fiscal year ending June 30, 1914," approved March 4, 1913 (37 Stat., 832).

Paragraph 3. *Viruses, serums, toxins, and analogous products.*—All viruses, serums, toxins, and analogous products, such as antitoxins, vaccines, tuberculins, malleins, microorganisms, killed microorganisms, and products of microorganisms which are intended for use in the treatment of domestic animals.

Paragraph 4. *The department.*—The United States Department of Agriculture.

Paragraph 5. *Bureau.*—The Bureau of Animal Industry of the United States Department of Agriculture.

Paragraph 6. *Bureau employee.*—Any officer, agent, or other individual employed in the Bureau of Animal Industry, who is authorized by the chief of the bureau to do any work or perform any duty in connection with the execution of the provisions of the virus-serum-toxin act of 1913.

Paragraph 7. *Licensed establishment.*—Any establishment holding an unexpired, unsuspended, and unrevoked license issued by the Secretary of Agriculture for the preparation of any virus, serum, toxin, or analogous product.

Paragraph 8. *Official station.*—One or more licensed establishments included under a single supervision.

Paragraph 9. *Inspector in charge.*—An inspector assigned to supervise and perform official work at an official station and who reports directly to the chief of bureau.

Paragraph 10. *Person.*—Natural persons, individuals, firms, partnerships, corporations, companies, societies, and associations, and every agent, officer, or employee of any thereof. This term shall import both the plural and the singular as the case may be.

Paragraph 11. *Serial number.*—A number given each batch of virus, serum, toxin, or analogous product to identify the said virus, serum, toxin, or analogous product with the records of preparation thereof.

Paragraph 12. *Immediate or true container.*—The unit, bottle, phial, ampul, tube, or other receptacle or container in which any virus, serum, toxin, or analogous product is customarily dispensed.

Paragraph 13. *Hog-cholera virus.*—The clear serum, plasma, or defibrinated blood, derived from hogs sick of hog cholera and free from other communicable diseases.

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Paragraph 14. *Anti-hog-cholera serum.*—The clear serum, plasma, or defibrinated blood, derived from immune hogs which have been sufficiently hyperimmunized by the injection of the virus of hog cholera, as well as concentrated or refined products containing the protective principles derived from such serum, plasma, or defibrinated blood.

Paragraph 15. *Return date.*—A date placed upon trade labels, affixed to immediate or true containers of viruses, serums, toxins, and analogous products, by the producers, to indicate the limit of time during which the said products may be expected to retain their full strength or potency.

REGULATION 2.—LICENSES AND INSPECTION.

SECTION 1. Every establishment in the United States at which any virus, serum, toxin, or analogous product is prepared for sale, barter, or exchange in the District of Columbia or in any Territory of or place under the jurisdiction of the United States, or for shipment or delivery for shipment from any State or Territory or the District of Columbia to any other State or Territory or the District of Columbia, shall hold an unexpired, unsuspended, and unrevoked license, issued by the Secretary of Agriculture, and shall have inspection under these regulations.

SECTION 2. All viruses, serums, toxins, and analogous products produced at establishments required by these regulations to hold licenses shall be prepared, handled, stored, marked, received for transportation, and transported as required by these regulations.

SECTION 3. Paragraph 1. The proprietor or operator of each establishment of the kind specified in section 1 of this regulation shall make application in writing to the Secretary of Agriculture for a license. When one proprietor conducts more than one establishment, a separate application shall be made for a license for each establishment. Blank forms of application will be furnished upon request addressed to the Bureau of Animal Industry, Washington, D. C.

Paragraph 2. Triplicate copies of plans, properly drawn to scale, and of specifications, including plumbing and drainage of establishments, together with triplicate copies of all labels and advertising matter to be used in connection with, or relating to, all viruses, serums, toxins, and analogous products prepared therein, shall accompany the application for a license.

Paragraph 3. In cases of change in ownership or location, while an application is pending or after a license has been issued, a new application shall be made.

SECTION 4. Paragraph 1. A license will not be issued unless the condition of the establishment and the methods of preparation are

such as reasonably to insure that the product will accomplish the object for which it is intended and that such product is not worthless, contaminated, dangerous, or harmful.

Paragraph 2. A license will not be issued unless and until the establishment is being operated under the direct supervision of a competent person trained in bacteriological technique and in the preparation of the viruses, serums, toxins, or analogous products named in the application.

Paragraph 3. A license will not be issued for the preparation of any virus, serum, toxin, or analogous product, if advertised so as to mislead or deceive the purchaser, or if the package or container in which the same is intended to be sold, bartered, exchanged, or shipped, bears or contains any statement, design, or device which is false or misleading in any particular.

SECTION 5. Paragraph 1. A license will be issued only after inspection of the establishment by a bureau employee has shown that the condition and equipment of the establishment and the methods of preparing, handling, storing, and marking are in conformity with these regulations.

Paragraph 2. Licenses shall be numbered and shall be in the following form:

UNITED STATES VETERINARY LICENSE NO. .....

WASHINGTON, D. C., ..., *191*.....

This is to certify that, pursuant to the terms of the act of Congress approved March 4, 1913 (37 Stat., 832), governing the preparation, sale, barter, exchange, shipment, and importation of viruses, serums, toxins, and analogous products intended for use in the treatment of domestic animals, ... is hereby licensed to maintain at..... Street, city or town of ....., State of ....., an establishment for the preparation of ..... during the calendar year 191....

This license is subject to suspension or revocation if the licensee violates or fails to comply with any provision of said act approved March 4, 1913, or of the regulations made thereunder.

[L. S.] .....

Secretary of Agriculture.

Countersigned:

.....

Chief, Bureau of Animal Industry.

Paragraph 3. Each license shall terminate at the end of the calendar year for which it is issued.

SECTION 6. Paragraph 1. No viruses, serums, toxins, or analogous products shall be prepared in whole or in part in a licensed establishment for any other licensed establishment unless authorized in advance by the chief of bureau.

Paragraph 2. Each licensed establishment shall be separate and distinct from any unlicensed establishment in which any virus, serum, toxin, or analogous product is prepared or handled.

Paragraph 3. When a license is issued the bureau shall inform the proprietor or operator of the establishment of the requirements of these regulations. If the establishment at the time the license is issued contain any viruses, serums, toxins, or analogous products, which have not theretofore been prepared, and of which the containers have not been theretofore marked, in compliance with these regulations, the identity of the same shall be maintained and it shall not be shipped or delivered for shipment from any State or Territory or the District of Columbia to any other State or Territory or the District of Columbia, or otherwise dealt with as a product prepared under these regulations. The establishment shall adopt and enforce all necessary measures, and shall comply with all such directions as the chief of bureau may prescribe for carrying out the purposes of this paragraph.

REGULATION 3.—PERMITS.

SECTION 1. Each importer of viruses, serums, toxins, or analogous products shall hold an unexpired, unsuspended, and unrevoked permit issued by the Secretary of Agriculture.

SECTION 2. Paragraph 1. Each importer of viruses, serums, toxins, and analogous products shall make application in writing to the Secretary of Agriculture for a permit. The application shall specify the port or ports of entry at which the imported articles will be cleared through the customs. Blank forms of application will be furnished upon request addressed to the Bureau of Animal Industry, Washington, D. C.

Paragraph 2. Each application for a permit shall be accompanied by the affidavit of the actual manufacturer produced before an American consular officer, giving the city or town where the viruses, serums, toxins, or analogous products mentioned therein are prepared, and stating that said products are not worthless, contaminated, dangerous, or harmful, whether the products were derived from animals, and if so derived, that such animals have not been exposed to any infectious or contagious disease, except as may be essential in the preparation of the products, and as specified in the affidavit.

Paragraph 3. Each application for a permit shall be accompanied by the written consent of the actual manufacturer that properly accredited employees of the department shall have the privilege of inspecting, without previous notification, all parts of the establishment at which such viruses, serums, toxins, or analogous products are prepared, and all processes of and all records kept relative to the preparation of such products at such times as may be demanded by the aforesaid employees.

Paragraph 4. Each application for permit shall be accompanied by triplicate copies of all labels and advertising matter.

SECTION 3. A permit will not be issued for the importation of any viruses, serums, toxins, or analogous products if advertised so as to mislead or deceive the purchaser, or if the package or container in which the same is intended to be sold, bartered, exchanged, shipped, or imported, bears or contains any statement, design, or device, which is false or misleading in any particular.

SECTION 4. Paragraph 1. Permits shall be numbered and shall be in the following form:

UNITED STATES VETERINARY PERMIT NO. ....

Washington, D. C., ..., 191....

This is to certify that pursuant to the terms of the act of Congress approved March 4, 1913 (37 Stat., 832), governing the preparation, sale, barter, exchange, shipment, and importation of viruses, serums, toxins, and analogous products intended for use in the treatment of domestic animals.....of....., State of ....., is hereby authorized, so far as the jurisdiction of the Department of Agriculture is concerned, to import.....manufactured by....., of....., into the United States through the port of.....during the calendar year 191....

This permit is subject to suspension or revocation if the permittee violates or fails to comply with the provisions of the said act approved March 4, 1913, or of the regulations made thereunder.

[L. S.] .....,

Secretary of Agriculture.

Countersigned:

.....,

Chief, Bureau of Animal Industry.

Paragraph 2. Each permit shall terminate at the end of the calendar year for which it is issued.

REGULATION 4.—SUSPENSION OR REVOCATION OF LICENSES AND PERMITS.

SECTION 1. Licenses or permits may be suspended or revoked after opportunity for hearing has been accorded the licensee or permittee if it appears—

(1) That the construction of the establishment in which the viruses, serums, toxins, or analogous products are prepared is defective, or that the establishment is improperly conducted;

(2) That the methods of preparation are faulty, or that the said products contain impurities or lack potency;

(3) That the products are advertised or labeled so as to mislead or deceive the purchaser in any particular;

(4) That the license or permit is used to facilitate or effect the preparation, sale, barter, exchange, shipment, or importation of any worthless, contaminated, dangerous, or harmful viruses, serums, toxins, or analogous products; or

(5) That the licensee or permittee has violated or failed to comply with any provision of the virus-serum-toxin act of 1913, or of the rules and regulations made thereunder.

SECTION 2. All hearings shall be private and at times and places designated by the Secretary of Agriculture. The parties interested may appear in person or by attorney, and may submit oral or written evidence on the questions involved.

REGULATION 5.—ASSIGNMENT OF BUREAU EMPLOYEES.

SECTION 1. Any bureau employee, as defined in these regulations, shall be permitted to enter any establishment licensed under these regulations at any hour during the day time or night time; and such bureau employee shall be permitted to inspect without previous notification the entire premises of the establishment, including all buildings, compartments, and other places, and all equipment such as chemicals, instruments, apparatus, and the like, as well as the methods used in, and all records maintained relative to, the preparation of any viruses, serums, toxins, or analogous products.

SECTION 2. Each bureau employee, as defined in these regulations, will be furnished with a numbered official badge, which he shall not allow to leave his possession. This badge shall be sufficient identification to entitle him to admittance at all regular entrances and to all parts of the licensed establishment and premises and to any place at any time for the purpose of making an inspection pursuant to section 1 of this regulation.

REGULATION 6.—FACILITIES FOR INSPECTION.

SECTION 1. When required by the chief of bureau or the inspector in charge, the following facilities, and such others as may be essential to efficient conduct of inspection, shall be furnished by each licensed establishment:

(*a*) Satisfactory pens, equipment, and assistance for conducting tests required in accordance with these regulations.

(*b*) Suitable rooms, compartments, and receptacles in such number and places as may be necessary for holding any viruses, serums, toxins, or analogous products for treatment or testing required in accordance with these regulations. Such rooms, compartments, and receptacles shall be equipped for secure locking and shall be held under locks furnished by the department, the keys of which shall not leave the custody of bureau employees.

REGULATION 7.—SANITATION.

SECTION 1. Paragraph 1. Triplicate copies of plans properly drawn to scale and of specifications, including plumbing and drainage, for remodeling plants of licensed establishments and for new structures, should be submitted to the chief of bureau in advance of construction.

Paragraph 2. Stables or other premises for animals used in the

production or testing of viruses, serums, toxins, or analogous products shall be properly ventilated and lighted, appropriately drained an guttered, and kept in good sanitary condition.

Paragraph 3. Animals infected with or exposed to any infectious, contagious, or communicable disease shall be properly segregated.

Paragraph 4. All hogs, before being admitted to any place where animals used in the preparation or testing of viruses, serums, toxins, or analogous products are held, shall be dipped as the chief of bureau shall prescribe. Animals shall not be removed from the premises of a licensed establishment without permission obtained in advance from the inspector in charge.

Paragraph 5. Licensed establishments shall be so located as to avoid the spread of disease, and suitable arrangements shall be made for the disposal of all refuse.

Paragraph 6. Direct communication to licensed establishments shall not be maintained from public stockyards, abattoir pens, or other places in which animals are received or held for any purpose.

Paragraph 7. All viruses, serums, toxins, and analogous products shall be prepared, handled, and distributed with due sanitary precautions, and all viruses, serums, toxins, or analogous products shipped or delivered for shipment shall be securely packed.

Section 2. Paragraph 1. The floors, walls, ceilings, partitions, posts, doors, and all other parts of all structures at licensed establishments shall be of such material, construction, and finish as will make them susceptible of being readily and thoroughly cleaned.

Paragraph 2. Separate rooms and compartments shall be provided for preparing, handling, and storing virulent or attenuated microorganisms or toxins, and for washing and sterilizing equipment, containers, instruments, and other apparatus.

Paragraph 3. All rooms and compartments shall have abundant light and sufficient ventilation to insure sanitary and hygienic conditions.

Section 3. Paragraph 1. Each licensed establishment shall have dressing rooms and toilet rooms and urinals sufficient in number, ample in size, conveniently located, properly ventilated, and meeting all requirements as to sanitary construction and equipment. These shall be separate from rooms and compartments in which any viruses, serums, toxins, or analogous products are prepared, handled, or stored.

Paragraph 2. Each licensed establishment shall have modern lavatory accommodations, including running hot and cold water, soap, towels, etc. These shall be located at such places in establishments as may be essential to assure cleanliness of all persons handling viruses, serums, toxins, or analogous products.

SECTION 4. There shall be an efficient drainage and plumbing system for the establishment and premises, and all drains and gutters shall be properly installed with approved traps and vents.

SECTION 5. The water supply, both hot and cold, shall be ample and clean. Adequate facilities shall be provided for the distribution of water in each establishment and for the washing of all equipment, containers, machinery, instruments, other apparatus, and animals used in the preparation, handling, or storing of any viruses, serums, toxins, or analogous products.

SECTION 6. All equipment, containers, instruments, and other apparatus used in the preparation, handling, or storing of any virus, serum, toxin, or analogous product shall be of such material, construction, and design as will make them susceptible of being readily and thoroughly cleaned and sterilized, and such equipment, containers, instruments, and other apparatus shall be handled so as to insure freedom from contamination. Equipment, containers, instruments, and other apparatus used for preparing, handling, or storing virulent or attenuated microorganisms or toxins shall not be used for handling, preparing, or storing other forms of biological products.

SECTION 7. All employees of the establishment who handle viruses, serums, toxins, or analogous products shall keep their hands and clothing clean. The hands of such employees shall not come in contact with any viruses, serums, toxins, or analogous products, or with any part of the equipment, containers, instruments, or other apparatus, which may come in contact with any such products.

SECTION 8. Caps, gowns, and other outer clothing worn by persons while handling any viruses, serums, toxins, or analogous products, or by those who enter any room, compartment, or place where any such products are being handled, shall be of clean white material.

SECTION 9. The outer premises of every licensed establishment, embracing docks, driveways, approaches, yards, pens, chutes, and alleys, shall be properly drained and kept in a clean and orderly condition. The accumulation on the premises of an establishment of any material in which flies may breed is forbidden. No nuisance shall be allowed in any licensed establishment or on its premises.

SECTION 10. Every practicable precaution shall be taken to keep establishments free of flies, rats, mice, and other vermin.

SECTION 11. All parts of the carcasses of animals producing viruses, all dead animals, all refuse, and all worthless, contaminated, dangerous, or harmful viruses, serums, toxins, or analogous products, shall be incinerated or otherwise destroyed by establishments in accordance with methods prescribed by the chief of bureau.

SECTION 12. All rooms, compartments, and other places used for preparing, handling, or storing viruses, serums, toxins, or analogous

products shall be kept clean and sanitary, and all equipment, containers, instruments, and other apparatus used in preparing, handling, or storing any such products shall be thoroughly cleaned and sterilized before use.

SECTION 13. Smoking or expectorating in any room, compartment, or place in which viruses, serums, toxins, or analogous products are prepared, handled, or stored is prohibited.

REGULATION 8.—STERILIZATION.

SECTION 1. All equipment, containers, instruments, and other apparatus, before being used in preparing, handling, or storing viruses, serums, toxins, or analogous products, shall be thoroughly sterilized by live steam at a temperature of at least 120° C. for not less than one-half hour or by dry heat at a temperature of at least 160° C. for not less than one hour. If for any reason such methods of sterilization are impracticable, then a process known to be equally efficacious in destroying microorganisms and their spores may be substituted after approval by the chief of bureau.

REGULATION 9.—STORAGE.

SECTION 1. Viruses, serums, toxins, and analogous products which may be injuriously affected by exposure to light or to high temperature shall be stored in a dark, cold chamber or refrigerator at a temperature of not to exceed 50° F. All dealers in the District of Columbia or any Territory or any place under the jurisdiction of the United States shall keep such products protected from light and under refrigeration until sold or otherwise disposed of.

REGULATION 10.—RECORDS.

SECTION 1. Paragraph 1. Permanent detailed records of the sources, of the preparation, of tests for purity and potency, and of methods of preservation, of each lot of viruses, serums, toxins, and analogous products shall be kept by each licensed establishment and by each manufacturer producing such products for importation into the United States.

Paragraph 2. Permanent detailed records, in a form satisfactory to the chief of bureau, shall be maintained by each licensed establishment and by each importer, showing the sale, shipment, or other disposition of the viruses, serums, toxins, and analogous products handled.

REGULATION 11.—LABELS.

SECTION 1. Paragraph 1. Each immediate or true container of viruses, serums, toxins, or analogous products; prepared for sale, barter, exchange, or shipment, by any licensed establishment, or imported into the United States, shall bear a trade label as hereinafter described.

Paragraph 2. No container which bears or is to bear a trade label shall be filled in whole or in part except with products which have been prepared in compliance with these regulations and which are not worthless, contaminated, dangerous, or harmful, and are strictly in accordance with the statements on the label.

SECTION 2. Paragraph 1. Trade labels shall bear the true name of the product contained in the package and, except as provided in section 3, regulation 16, and section 4, regulation 17, respectively, shall bear the license or permit number assigned by the department in the following form: "U. S. Veterinary License No.____" or "U. S. Veterinary Permit No. ____," or abbreviations thereof approved by the chief of bureau.

Paragraph 2. Each trade label shall bear a serial number affixed by the manufacturer for identification of the product, with the records of preparation thereof.

Paragraph 3. Each trade label shall bear a return date.

Paragraph 4. Each trade label shall bear a dosage table governing the use of the product contained therein and such other information as may be required by the chief of bureau.

SECTION 3. Copies of all trade labels shall be submitted in triplicate to the chief of bureau before use.

SECTION 4. When any virus, serum, toxin, or analogous product is prepared by a licensed establishment, or imported, for a person other than one to whom a license or permit has been granted, and the name of the person is to appear on the label or container thereof, a statement shall be made on the label to the effect that the virus, serum, toxin, or analogous product was prepared for such person, or the term "distributer," "distributers," "distributed by," or other equivalent term, shall be used thereon in connection with the name of such person. When the name of such person appears on the label it shall be prominently placed and lettered and shall not be used so as to be either false or misleading.

REGULATION 12.—COLLECTING SAMPLES.

SECTION 1. Paragraph 1. Samples of viruses, serums, toxins, and analogous products shall be collected by authorized officers, agents, or employees of the department.

Paragraph 2. Samples may be purchased in the open market and the marks, brands, or tags upon the package or wrapper thereof shall be noted. The collector shall note the names of the vendor and agent of the vendor who made the sale, together with the date of purchase. The collector shall purchase representative samples.

Paragraph 3. All samples or parts of samples shall be sealed by the collector and marked with identifying marks.

REGULATION 13.—REPORTS.

SECTION 1. Paragraph 1. Reports of the work of inspection carried on in every licensed establishment shall be forwarded to the bureau by the inspector in charge in such form and manner as may be specified by the chief of bureau.

Paragraph 2. Each licensed establishment shall furnish to the bureau employees accurate information as to all matters needed by them for making their reports pursuant to paragraph 1 of this section.

REGULATION 14.—ADMISSION AND USE OF ANIMALS.

SECTION 1. Paragraph 1. No animal from public stockyards, abattoir pens, or similar places, and no animal which is infected with or which has been exposed to any infectious, contagious, or communicable disease shall be brought onto the premises of any licensed establishment.

Paragraph 2. Except as provided in paragraph 1, section 1, regulation 17, viruses, serums, toxins, or analogous products shall not be derived from animals infected with or exposed to any infectious, contagious, or communicable disease other than is essential in the preparation of the product.

Paragraph 3. Each licensed establishment shall adopt such measures as the chief of bureau shall from time to time prescribe for carrying out the provisions of this regulation.

REGULATION 15.—RETESTING.

SECTION 1. Viruses, serums, toxins, and analogous products, the containers of which bear United States veterinary license numbers or United States veterinary permit numbers, or any other mark required by these regulations, shall be subject to inspection at any time or place. If it appears as a result of such inspection that any such product, even though prepared in a licensed establishment or imported under permit issued by the Secretary, is worthless, contaminated, dangerous, or harmful, the Secretary shall give notice to the manufacturer or importer thereof, and to any jobbers, dealers, or other persons known to have any of such product in their possession. Unless and until the Secretary shall otherwise direct, no person so notified shall thereafter sell, barter, or exchange in any place under the jurisdiction of the United States nor shall thereafter ship or deliver for shipment from any State, Territory, or the District of Columbia to any other State, Territory, or the District of Columbia, any of such product.

REGULATION 16.—HOG-CHOLERA VIRUS.

SECTION 1. All hog-cholera virus intended for simultaneous inoculation shall be derived from hogs inoculated by the establishment and which react in a satisfactory manner as defined by the chief of bureau.

SECTION 2. All hog-cholera virus shall be treated and tested by the establishment in accordance with methods prescribed by the chief of bureau.

SECTION 3. Each immediate or true container of hog-cholera virus which has been tested and found not to be worthless or contaminated shall have affixed thereto, in a manner prescribed by the chief of bureau, a numbered stamp or other device furnished by the department, bearing the license number of the establishment in the following form: "U. S. Veterinary License No. ____". On and after January 1, 1916, the United States veterinary license number shall not appear in any other place on the immediate or true containers of hog-cholera virus.

SECTION 4. Paragraph 1. The trade label on each immediate or true container of hog-cholera virus shall bear the word "CAUTION" or "DANGEROUS" prominently placed and lettered, together with the statement "Destroy this container, together with all unused contents, by heat."

Paragraph 2. The "return date" on the trade label on each immediate or true container of hog-cholera virus shall be a date not more than 30 days later than the date of preparation.

SECTION 5. The following special facilities shall be provided by each establishment licensed to prepare hog-cholera virus:

(*a*) Separate operating rooms.

(*b*) Separate rooms in which the hogs shall be washed, cleaned, and otherwise prepared before being taken into the operating room.

(*c*) Separate rooms for conducting autopsies.

(*d*) Separate rooms or compartments for bottling.

(*e*) Clean cloths, dampened with a disinfectant, to be used for covering hogs during all operations incident to the preparation of hog-cholera virus.

(*f*) All doors, windows, or other openings shall be equipped with dust screens.

SECTION 6. All persons before entering any room, compartment, or place where hog-cholera virus is prepared, handled, or stored, or any place where animals used in the preparation or testing of hog-cholera virus are held, shall change their outer clothing and shoes or cover the same by the use of gowns and overshoes, so as to prevent the introduction of infectious, contagious, or communicable diseases.

REGULATION 17.—ANTI-HOG-CHOLERA SERUM.

SECTION 1. Anti-hog-cholera serum shall be derived only from hyperimmune hogs. All hogs from which any hog-cholera serum is derived shall be subjected to post-mortem examination, and if it appears on such examination that any hog was so affected with any infectious, contagious, or communicable disease as to render the serum contaminated, dangerous, or harmful, the serum shall be destroyed by the establishment under the supervision of a bureau employee.

SECTION 2. Excepting serum derived from hogs which prior to hyperimmunization were found upon examination, including the tuberculin test, to be free from any infectious, contagious, or communicable disease, the anti-hog-cholera serum derived from each hyperimmune hog shall be kept separate and apart from any other serum until it has been found on post-mortem examination that the hog was not so infected with infectious, contagious, or communicable disease as to render the serum contaminated, dangerous, or harmful.

SECTION 3. All anti-hog-cholera serum shall be treated and tested by the establishment in accordance with methods prescribed by the chief of bureau.

SECTION 4. Each immediate or true container of anti-hog-cholera serum which has been tested and found not to be worthless, contaminated, dangerous, or harmful, shall have affixed thereto, in a manner prescribed by the chief of bureau, a numbered stamp or other device furnished by the department, bearing the license number of the establishment in the following form: "U. S. Veterinary License No. ____." On and after January 1, 1916, the United States veterinary license number shall not appear in any other place on the immediate or true containers of anti-hog-cholera serum.

SECTION 5. The following special facilities shall be provided by each establishment licensed to prepare anti-hog-cholera serum:

(*a*) Separate operating rooms.

(*b*) Separate rooms in which the hogs shall be washed, cleaned, and otherwise prepared before being taken into the operating room.

(*c*) Separate rooms for conducting autopsies.

(*d*) Separate rooms or compartments for bottling.

(*e*) Clean cloths, dampened with a disinfectant, to be used for covering hogs during all operations incident to the preparation of anti-hog-cholera serum.

(*f*) All doors, windows, or other openings shall be equipped with dust screens.

SECTION 6. All persons before entering any room, compartment, or place where anti-hog-cholera serum is prepared, handled, or stored, or any place where animals used in the preparation or testing of anti-hog-cholera serum are held, shall change their outer clothing

and shoes or cover the same by the use of gowns and overshoes, so as to prevent the introduction of infectious, contagious, or communicable diseases.

REGULATION 18.—VACCINES, BACTERINS, AND TOXINS.

SECTION 1. Paragraph 1. Viruses entering into the preparation of vaccines, bacterins, and toxins shall be derived from animals which are affected with no other disease than that for which the vaccines, bacterins, or toxins are intended to be used.

Paragraph 2. All vaccines, bacterins, and toxins shall be derived from the specific cause of the disease for which they are intended to be used, or from the secondary invaders of the respective diseases.

SECTION 2. All vaccines, bacterins, and toxins shall be tested by the establishment in accordance with methods prescribed by the chief of bureau.

SECTION 3. Paragraph 1. The trade labels on the immediate or true containers of vaccines, bacterins, and toxins shall bear statements indicating the diseases for which they are intended to be used or the viruses from which they are prepared.

Paragraph 2. The "return date" on the trade label of any blackleg vaccine shall be a date not more than six months later than the date of preparation. The "return date" on the trade label of anthrax vaccine, prepared by the Pasteur method, shall be a date not more than three months later than the date of preparation.

REGULATION 19.—ANTITOXINS AND SERUMS.

SECTION 1. Paragraph 1. All antitoxins and serums shall be tested by the establishment in accordance with methods prescribed by the chief of bureau.

Paragraph 2. The immunity unit for measuring the strength of tetanus antitoxin shall be 10 times the least quantity of antitetanic serum necessary to save the life of a 350-gram guinea pig for 96 hours against the official test dose of the standard toxin furnished by the Hygienic Laboratory of the United States Public Health Service. The number of immunity units recommended for the prevention of tetanus in a horse shall be at least 500 units.

SECTION 2. The trade labels of antitoxins and serums shall bear statements indicating the disease for which they are intended to be used or the specific toxins or viruses which have been employed in their preparation.

REGULATION 20.—TRANSPORTATION.

SECTION 1. No carrier or other person shall transport or receive for transportation from any State or Territory or the District of Columbia to any other State or Territory or the District of Columbia,

or to any place under the jurisdiction of the United States, any virus, serum, toxin, or analogous product unless and until a certificate is made and furnished to him in one of the forms prescribed therefor in this regulation.

SECTION 2. Paragraph 1. For the purposes of these regulations the United States parcel post shall be deemed a carrier, and the provisions of these regulations relating to transportation by carriers shall apply, so far as may be applicable, to transportation by parcel post.

Paragraph 2. For the purposes of these regulations every ferry and ferry line shall be deemed a carrier, and the provisions of these regulations relating to transportation by carriers shall apply to transportation by ferry or ferry line of any virus, serum, toxin, or analogous product loaded on a truck, wagon, cart, or other vehicle, or otherwise prepared for transportation.

SECTION 3. Jobbers, wholesalers, branch houses of licensed establishments, and others who receive viruses, serums, toxins, and analogous products which have been prepared and the containers marked in compliance with these regulations shall not break bulk, repack, and ship the same from any State or Territory or the District of Columbia to any other State or Territory or the District of Columbia, or to any place under the jurisdiction of the United States, but such virus, serum, toxin, or analogous product may only be shipped in the original container and under the original label.

SECTION 4. When any virus, serum, toxin, or analogous product prepared in compliance with these regulations is offered to any carrier for transportation from any State or Territory or the District of Columbia to or through any other State or Territory or the District of Columbia, or to any place under the jurisdiction of the United States, the carrier shall require and the shipper shall make and deliver to the carrier a certificate in the following form:

Date..... Name of carrier.....
Shipper..... Point of shipment.....
Consignee..... Destination.....

I hereby certify that the following described viruses, serums, toxins, or analogous products which are offered for shipment have been prepared at an establishment holding an unsuspended and unrevoked United States veterinary license under the virus-serum-toxin act of 1913 (37 Stat., 832), and at this date are not worthless, contaminated, dangerous, or harmful. Kind of product.....; amount of product.....

.....
(Signature of shipper.)

.....
(Address of shipper.)

The signature of the shipper or of his agent shall be written in full. This certificate may be stamped upon, or incorporated in, any

form which is ordinarily used in the transportation of viruses, serums, toxins, or analogous products. Certificates of this form or copies thereof need not be forwarded to the department at Washington.

SECTION 5. When any virus, serum, toxin, or analogous product imported into the United States in compliance with these regulations is offered to any carrier for transportation from any State or Territory or the District of Columbia to or through any other State or Territory or the District of Columbia, or to any place under the jurisdiction of the United States, the carrier shall require and the shipper shall make and deliver to the carrier a certificate in the following form:

Date..... Name of carrier.....
Shipper..... Point of shipment.....
Consignee..... Destination.....

I hereby certify that the following-described viruses, serums, toxins, or analogous products which are offered for shipment have been imported by an importer holding an unsuspended and unrevoked United States veterinary permit under the virus-serum-toxin act of 1913 (37 Stat., 832), and at this date are not worthless, contaminated, dangerous, or harmful. Kind of product.....; amount of product.....; United States veterinary permit No. .....

.....
(Signature of shipper.)

.....
(Address of shipper.)

The signature of the shipper or his agent shall be written in full. This certificate may be stamped upon, or incorporated in, any form that is ordinarily used in the transportation of viruses, serums, toxins, or analogous products. Certificates of this form or copies thereof need not be forwarded to the department at Washington.

SECTION 6. All waybills, transfer bills, running slips, or conductor's cards, accompanying a shipment from any State or Territory or the District of Columbia to or through any other State or Territory or the District of Columbia, or to any place under the jurisdiction of the United States, of any virus, serum, toxin, or analogous product, shall have embodied therein, stamped thereon, or attached thereto a signed statement, which shall be evidence to connecting carriers that the proper shippers' certificate, as required by section 4 of this regulation, is on file with the initial carrier; and no connecting carrier shall receive for transportation or transport from any State or Territory or the District of Columbia to or through any other State or Territory or the District of Columbia, or to any place under the jurisdiction of the United States, any shipment of virus, serum, toxin, or analogous product, unless the waybill, transfer bill, running slip, or conductor's card accompanying the same includes the aforesaid signed statement in one of the following forms:

When shipment is made under section 4:

..... (name of transportation company). U. S. veterinary licensed as evidenced by shipper's certificate on file with initial carrier.

(Signed) ....., *Agent.*

When shipment is made under section 5:

..... (name of transportation company). U. S. veterinary permitted as evidenced by shipper's certificate on file with initial carrier.

(Signed) ....., *Agent.*

Signatures of agents to statements required under this section shall be written in full.

SECTION 7. All original certificates delivered to a carrier in accordance with these regulations shall be filed separate and apart from all its other papers and records and retained by it for one year in order that they may be readily checked in such manner as the Secretary of Agriculture may from time to time prescribe.

THE VIRUS-SERUM-TOXIN LAW.

[Extract from "An act making appropriations for the Department of Agriculture for the fiscal year ending June thirtieth, nineteen hundred and fourteen," approved March 4, 1913 (37 Stat., 832).]

That from and after July first, nineteen hundred and thirteen, it shall be unlawful for any person, firm, or corporation to prepare, sell, barter, or exchange in the District of Columbia, or in the Territories, or in any place under the jurisdiction of the United States, or to ship or deliver for shipment from one State or Territory or the District of Columbia to any other State or Territory or the District of Columbia, any worthless, contaminated, dangerous, or harmful virus, serum, toxin, or analogous product intended for use in the treatment of domestic animals, and no person, firm, or corporation shall prepare, sell, barter, exchange, or ship as aforesaid any virus, serum, toxin, or analogous product manufactured within the United States and intended for use in the treatment of domestic animals, unless and until the said virus, serum, toxin, or analogous product shall have been prepared, under and in compliance with regulations prescribed by the Secretary of Agriculture, at an establishment holding an unsuspended and unrevoked license issued by the Secretary of Agriculture as hereinafter authorized. That the importation into the United States, without a permit from the Secretary of Agriculture, of any virus, serum, toxin, or analogous product for use in the treatment of domestic animals, and the importation of any worthless, contaminated, dangerous, or harmful virus, serum, toxin, or analogous product for use in the treatment of domestic animals, are hereby prohibited. The Secretary of Agriculture is hereby authorized to cause the Bureau of Animal Industry to examine and inspect all viruses, serums, toxins, and analogous products, for use in the treatment of domestic animals, which are being imported or offered for importation into the United States, to determine whether such viruses, serums, toxins, and analogous products are worthless, contaminated, dangerous, or harmful, and if it shall appear that any such virus, serum, toxin, or analogous product, for use in the treatment of domestic animals, is worthless, contaminated, dangerous, or harmful, the same shall be denied entry and shall be destroyed or returned at the expense of the owner or importer. That the Secretary of Agriculture be, and hereby is, authorized to make and promulgate from time to time such rules and regulations as may be necessary to prevent the preparation, sale, barter, exchange, or shipment as aforesaid of any worthless, contaminated, dangerous, or harmful virus, serum, toxin, or analogous product for use in the treatment of domestic animals, and to issue, suspend, and revoke licenses for the maintenance of establishments for the preparation of viruses, serums, toxins, and analogous products, for use in the treatment of domestic animals, intended for sale, barter, exchange, or shipment as aforesaid. The Secretary of Agriculture is hereby authorized to issue permits for the importation into the United States of viruses, serums, toxins, and analogous products, for use in the treatment of domestic animals, which are not worthless, contaminated, dangerous, or harmful. All licenses issued under authority of this Act to establishments where such viruses, serums, toxins, or analogous products are prepared for sale, barter, exchange, or shipment as aforesaid, shall be issued on condition that the licensee shall permit the inspection of such establishments and of such products and their preparation; and the Secretary of Agriculture may suspend or revoke any permit or license issued under authority of this Act, after opportunity for hearing has been granted the licensee or importer, when the Secretary of Agriculture is satisfied that such license or permit is being used to facilitate or effect the preparation, sale, barter,

exchange, or shipment as aforesaid, or the importation into the United States of any worthless, contaminated, dangerous, or harmful virus, serum, toxin, or analogous product for use in the treatment of domestic animals. That any officer, agent, or employee of the Department of Agriculture duly authorized by the Secretary of Agriculture for the purpose may, at any hour during the daytime or nighttime, enter and inspect any establishment licensed under this Act where any virus, serum, toxin, or analogous product for use in the treatment of domestic animals is prepared for sale, barter, exchange, or shipment as aforesaid. That any person, firm, or corporation who shall violate any of the provisions of this Act shall be deemed guilty of a misdemeanor, and shall, upon conviction, be punished by a fine of not exceeding $1,000 or by imprisonment not exceeding one year, or by both such fine and imprisonment, in the discretion of the court.

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